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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Masahiko KOIKE et al.
Title:	METHODS OF PRODUCING A COATED PREPARATION
Appl. No.:	10/520,747
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Examiner:	Jeffrey T. Palenik
Art Unit:	1615
Confirmation No.	3250

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam/Sir:

I, Masahiko Koike, the undersigned, a citizen of Japan residing at 2-2-29, Senrien, Toyonaka-shi, Osaka 560-0046, Japan do hereby declare:

I have been employed by Takeda Pharmaceutical Company Limited, Osaka, Japan, the Assignee of the above-identified application, since April 1991, and have been engaged in pharmaceutical research of said company.

I graduated from Toyama Medical and Pharmaceutical University with a degree of Master of Science in March 1991. I was also a visiting scientist in the Department of Industrial and Physical Pharmacy at Purdue University from April 2005 to March 2006.

I am one of the co-inventors of the above-identified patent application.

The following experiments were carried out by myself or under my direction:

Experiment

The dissolution property of pioglitazone hydrochloride between the preparation obtained according to Example 1 of the present Specification ("**Example 1**") and the preparation obtained according to Comparative Example 1 described below was compared according to the dissolution test described below.

Comparative Example 1

A pharmaceutical preparation containing 500 mg of metformin hydrochloride/16.53 mg of pioglitazone hydrochloride was obtained in the same manner as described in Example 1 of the present Specification, except that distilled water (270 g) was used in place of ethanol (170 g).

Dissolution test

For the preparations of Example 1 and Comparative Example 1, the dissolution property of pioglitazone hydrochloride in these preparations at 15, 30, 45, and 60 minutes was evaluated by rotating basket method (100 rpm) using 900 mL of 0.3M KCl-HCl buffer solution (37 °C, pH 2.0). The results are shown in Table A.

Table A. Dissolution (%) of pioglitazone hydrochloride

Time	15 min	30 min	45 min	60 min
Comparative Example 1	33.6	46.3	56.4	63.2
Example 1	69.3	77.7	85.5	91.4

As is evident from Table A, the preparation of Example 1 showed superior dissolution property of pioglitazone hydrochloride as compared to that of Comparative Example 1.

I further declare that all statements made in this declaration of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of legal decisions of any nature based on them, including the validity of any patent issuing from the captioned application.

4 June, 2009
Date

Masahiko Koike
Masahiko Koike